

REMARKS

This application is a continuation of U.S. Application 09/941,030 (the "Parent Application"). The Claims 1, 3, 16 and 17 of the Parent Application were rejected under 35 U.S.C. §103(a) as being obvious in view of U.S. Patent 4,950,240 to Greenwood ("Greenwood") in combination with U.S. Patent 3,179,107 to Clark ("Clark") and in further view of U.S. Patent 5,336,200 to Streck ("Streck"). As discussed below, there is no basis for combining these references as proposed by the Examiner to achieve the claimed invention. Consequently, the application is believed to be in condition for allowance.

As discussed during prosecution of the Parent Application, the Examiner states that *Clark* discloses a hypodermic unit having a barrel 10 with a tip 30, a needle assembly (20, 22), a plunger with proximal and distal portions (16, 18) connected together, a collar 32 and at least one deflectable locking tab 34 projecting inwardly from the collar. The Examiner admits that *Clark* fails to disclose a syringe having a plunger with proximal and distal portions connected by a breakable connection.

It is noted that *Greenwood* discloses a syringe having a piston 40 formed of a resilient rubber material and defining an interior cavity 48. The syringe further includes a beam plate 44 fitted within the bore 14 and attached to piston 40. (*See Col. 5, Ins. 1-3*). The beam plate 44 includes a center aperture 46 and inwardly extending beam members 50 and 51 joined to the beam member by fulcrums 52 and 53. (*See Col. 5, Ins. 3-6*). The syringe also includes a driver 12, having a having an end flange 36 with a breaker ring 62 extending downwardly therefrom. (*See Col. 5, Ins. 14-16*). A retractor shaft 61 having a diameter smaller than aperture 46 of beam plate 44 extends from breaker ring 62 through aperture 46 into the interior of cavity 43 of piston 40. (*See Col. 5, Ins. 16-20*). A retractor head 60 is joined to retractor shaft 61 so that retractor head 60 is captivated within cavity 42 by beam plate 44 and beams 50n and 51 and is joined to breaker ring 62 by retractor shaft 61. (*See Col. 5, Ins. 19-24*). "Beam plate 44 is constructed of brittle material such as acrylic." (*Col. 5, Ins. 66-67*).

As recited in *Greenwood*, the downward motion of driver 12 forces breaker ring 62 against beam member 50 and 51. The beam members are unable to support the downward force and therefore, the beam members break at fulcrums 52 and 53, as shown in Fig. 4. (*See Col. 7, Ins. 38-55*). "[T]he continuing downward motion of the driver 12. . . will bring retractor head 60 into contact with tapered surface 48 of cavity 43. Thereafter, the force

applied by the driver 12 to piston 40 via disk 44 causes a corresponding downward motion of piston 40 which in turn expels the captivated fluid within bore 14. . .” (Col. 7, Ins. 56-62). At the completion of the downward stroke, the fluid has been expelled and the beam members are completely severed from the beam plate. Thus, any subsequent withdrawal of the driver from the barrel “is no longer effective because of the absence of beam members 50 and 51.” (Col. 8, Ins. 3-4). Therefore, during the normal operation of the syringe, while the injection stroke is occurring, the beam members are broken, rendering the syringe inoperable after the completion of the injection stroke. *Greenwood* teaches that the beam plate is constructed of brittle material so that this breakage occurs during the downward stroke of the driver. Thus, the beam plate is unable to withstand the force associated with the normal operation of the syringe.

The Examiner contends that it would have been obvious to substitute a non-reusable plunger, such as in *Greenwood*, with a hypodermic unit of Clark, and/or with the grooved needle hub of Streck to achieve the claimed invention. This contention is unsupported by the evidence of record. “It is fundamental that rejections under 35 U.S.C §103 must be based on *evidence* comprehended by the language of that section.” *In re Grasselli*, 713 F.2d 731, 739 (Fed. Cir. 1983) (emphasis added). “[P]articular finds must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.” *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). In the Parent Application, the Examiner has merely asserted that it would have been obvious to substitute a plunger that prevents reuse with one that permits reuse. Beyond that Examiner’s assertion, there is no evidence supporting this conclusion. The Examiner assumes that “the problem to be solved is the reuse of hypodermic syringes”. While this is certainly an advantage of certain aspects of the invention, the full scope of the invention can only be understood by looking at each of the claims. It is inappropriate to pick and choose from various features of different prior art devices, arguing that one would have combined them to achieve their various benefits when the only suggestion to make the combination comes from the claim itself. Applicant’s attorney respectfully asserts that no *prima facie* case of obviousness has been made.

Even if the Examiner were to combine the references, they simply do not teach each of the claimed elements of the claims. Looking specifically at independent claims 1 and 6, this aspect of the invention is directed to a syringe including, *inter alia*, a plunger having a proximal portion and a distal portion that are connected by a breakable connection. This

breakable connection is structurally configured to withstand forces exerted during operation of the syringe for aspiration and injection, and yet to break upon the exertion of a breaking force greater than the operation force. This breakable connection is a structural element not present in Greenwood, or the other references relied upon by the Examiner.

Independent claim 9 recites a syringe having a plunger with means for allowing the plunger to break upon the exertion of a breaking force greater than the operation force exerted during use of the syringe during aspiration and injection. Again, neither Greenwood nor the other references relied upon by the Examiner teach or suggest this structure.

Without discussing each in detail, it will be appreciated that the dependent claims recite additional features that are not taught or suggested by the prior art.

As it is believed that the current claims address the concerns of the Examiner related to the Parent Application. Allowance is therefore earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney, Jeanne Lukasavage, at (201) 847-6797 in order to overcome any additional objections which he might have.

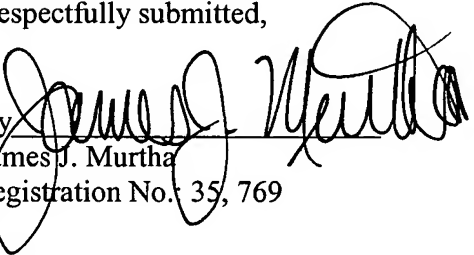
If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 02-1666 therefor.

Dated: November 11, 2003

BECTON, DICKINSON AND COMPANY
1 Becton Drive
Franklin Lakes, New Jersey 07417
201-847-6797

72083

Respectfully submitted,

By 
James J. Murtha
Registration No. 35, 769